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THE DEVELOPMENT AND VALIDATION OF A DIGITAL PEAK RESPIRATORY PRESSURE MONITOR AND ITS CHARACTERISTICS IN HEALTHY HUMAN SUBJECTS*

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Abstract : A digital peak respiratory pressure (DPRP) monitor for determining maximum inspiratory pressure (MIP) and maximum expiratory pressure (MEP) was developed using a pressure transducer and an analog to digital converter. It was calibrated using a mercury manometer. Human studies were conducted in healthy young adults in order to determine within-subject and inter-individual variability, as well as diurnal variations and gender differences in maximal respiratory pressures. The calibration studies for the instrument indicated that the instrument recorded accurate pressures, with little temporal drift. Within-subject variability was generally low while inter-individual variability was higher and significant. Gender differences were similar to those recorded in literature for other racial groups. The DPRP monitor described is inexpensive, accurate and portable, making it ideal for use at the patient's bedside.

Key words : lung function tests respiratory pressures

INTRODUCTION

The simplest way to test respiratory muscle strength is to measure maximal inspiratory (MIP) and expiratory pressures (MEP) at the mouth (1). The utility of these measures has been reviewed (2). MEP, for instance is useful in determining the ability of a person to cough effectively (3). This is of relevance to clinicians in trying to predict when a patient is at risk of developing atelectasis, pneumonia or gas exchange abnormalities because of an ineffective cough. MIP is used either alone (4) or together with mean inspiratory pressure per breath (5) in establishing when to wean patients off mechanical ventilators. More recently, the predictive value of MIP in relation to successful weaning off ventilators has been questioned (6). Nevertheless, together, these pressures provide a composite estimate of respiratory muscle strength and have been used in the assessment of patients with respiratory failure (7), chronic obstructive pulmonary disease (8) and neuromuscular disorders (3). Measurements of these pressures have been carried out in healthy, Caucasian populations (9, 10)

The measurement of maximal respiratory pressures is incorporated into

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some lung function measurement devices. In order to be truly useful, however, the instrument needs to be affordable and portable, allowing for the measurement of these parameters at the patient's bedside. These were the two major issues that governed our decision to devise a portable digital peak respiratory pressure (DPRP) monitor.

This paper describes the design and calibration of the DPRP monitor that we devised. Once calibrated, the instrument was subjected to human use, with the aim of establishing the following characteristics:

i) The intra and inter-individual variation in maximal inspiratory and expiratory pressures in healthy young adults.

ii) the presence and extent, if any, of a "training effect" in the measurement of MEP and MIP both in the short and long term.

iii) the variations in MEP and MIP during the waking hours of a single day.

iv) The relationship between MEP and MIP in a group of healthy subjects encompassing a wide range of body weights.

METHODS

Design of the Instrument

The following components were used in the design of the instrument.

i) Pressure Transducer: (Type 2A 0376, National Semi Conductors, Japan) with a range of −100 mm Hg to + 300 mm Hg (1 mv = 10 mm Hg) and a sensitivity of ± 1 mm Hg.

ii) Differential amplification and Linearization: Achieved using a Type upc 324C Operational amplifier (Op-amp).

iii) Analog to digital converter: Consisting of an 8 bit analog to digital converter (Type MC 14433P) with a sampling rate of 200/sec.

iv) Display driver: Consisting of a binary coded decimal (BCD) counter.

v) Display unit: a seven segment cold cathode type of display.

vi) Power supply: A 9V DC power supply was used to supply to all the sections.

vii) Resetting switch: This set the initial reading on the display to 96 mm Hg while recording the negative pressure.

viii) Mouth piece: was constructed according to the specifications laid down by Black and Hyatt (9) and consisted of a hollow PVC tube 15 cm in length, closed by a PVC cap at one end with a 2 mm hole in the center. The other end was connected to a PVC reducer. The thickness of the tube was 2 mm, with an internal diameter of 3 cm. The bottom of the tube was connected to a three way stop cock and and linked to the pressure transducer by a 50 cm. rubber tube. The assembly of these components is depicted in Fig 1. The entire assembly is smaller in size than a portable ECG machine.

Calibration of the Instrument

i) Calibration of positive pressures: A Mercury manometer and the DPRP Monitor were connected to a sphygmomanometer bulb via a 'T' type connector and pressure tubing. The bulb was compressed to achieve pressure rises in the mercury manometer

of 10 mm Hg steps between 0 and 160 and 20 mm Hg steps thereafter. The corresponding pressure changes in the DPRP monitor were noted.

ii) Calibration of negative pressures: was done using a similar arrangement as for positive pressure calibration with some modifications.

a) The sphygmomanometer bulb was replaced by a 50 cc syringe allowing for the generation of negative pressure by suction.
b) The pressure tubing was attached to the top of the Mercury manometer.
c) The DPRP monitor was reset to 96 mm Hg. Thus a reading of 86 mm Hg actually represented a pressure of – 10 mm Hg.

iii) "Drift" of the instrument: In order to determine the stability of the instrument with time the DPRP monitor was put on and the "Zero" pressures monitored every 15 minutes for a duration of 8 hours. Drift from the 96 mm Hg "reset" value for the record of negative pressures was done during Protocol 2 outlined below.

Human protocols

Subject instructions: In all instances, three measurements were performed for both MEP and MIP with the subjects standing up, and the maximal value for each used as the representative value. MEP was measured from total lung capacity, after a maximum inspiration and MIP from residual volume after a maximum expiration, as done earlier (9, 11).

Protocol 1: was developed to assess the intra and inter-individual variation within each measurement period and from day to day and week to week in 10 healthy subjects (7 male, 3 female). 5 subjects were randomly assessed on days 1, 2 and 9 while the remaining 5 subjects were assessed on drugs 1, 8, and 9 as in earlier studies on variability (12, 13, 14). This randomisation was done to exclude an effect of "order". Comparisons between days 1 and 2 and 8 and 9 allowed for the assessment of day to day variation. Comparison between days 2 and 9, and 1 and 8 allowed for the estimation of week to week variation. An effect of "short term training" was determined by comparing the three repetitions of MEP and MIP obtained on the first day of measurement. "Long term training" was assessed by comparing the maximal pressures obtained on the three separate days of measurement within a 9 day period.

Protocol 2: assessed the variations in 9 healthy subjects of MEP and MIP during the waking hours of the day (4 male, 5 female). MEP and MIP were measured for a 12 hour period during the day at intervals of one hour between 8 am and 7 pm.

Protocol 3: 47 healthy subjects (22 males and 25 females) of varying body sizes (Body mass index: 16.0 to 32.8 kg/m^2) were assessed for their MEP and MIP in order to determine:

a) whether there was a linear relationship between MEP and MIP in Indian subjects.
b) whether the nature of this relationship was in concordance with earlier reports of other ethnic groups from literature (4).
c) the nature of gender difference in the two parameters.

Statistical analysis

All data are expressed as mean ± SD. True intra-individual and inter-individual variation was obtained by calculating the Coefficient of Variation (CV) from the Two-way ANOVA table as previously described (12). All serial measurements were analysed using a Repeated Measures analysis of variance. Linear associations between variables were tested using Pearson's Correlations. In all instances the null hypothesis was rejected at $P<0.05$.

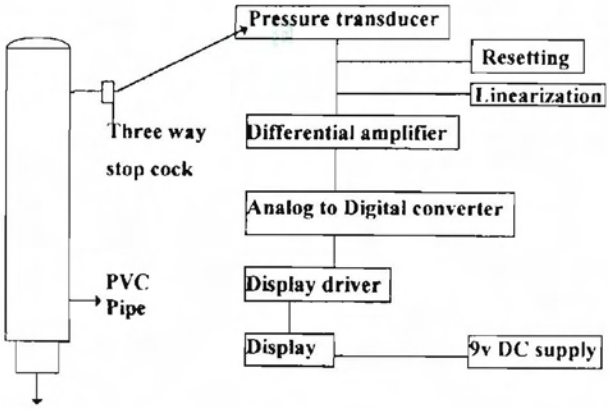

Fig. 1 : Components and assembly of the Digital Peak Respiratory Pressure Monitor.

RESULTS

During calibration procedures, the DPRP monitor recorded pressures that were close to those indicated with the mercury manometer, the maximum deviation from the pressures recorded with the manometer being no more than 1 mm Hg in either direction. The inter-instrument correlation for positive pressures between 0–250 mm Hg was strong and highly significant ($r = 0.99$, $P<0.001$). Similar results were obtained during calibration of negative pressures between 0 and −90 mm Hg. ($r = 0.99$, $P<0.001$) (Fig. 2). The drift in 'zero' in the instrument was no more than 1 mm Hg in either direction over a period of 8 hours. The drift in 'preset' value of 96 mm Hg was no more than 2 mm Hg for the same period.

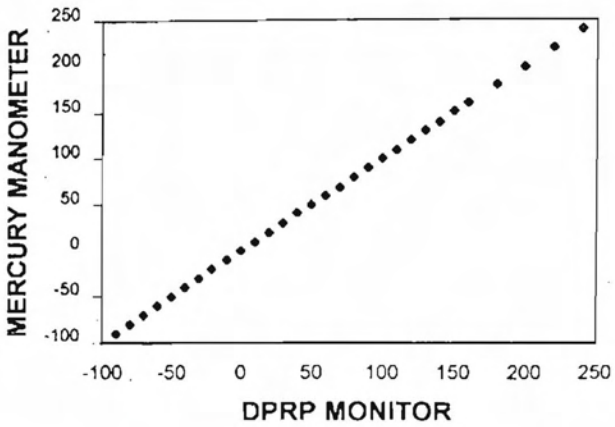

Fig. 2 : A comparison of positive and negative pressures recorded with the DPRP Monitor and Mercury Manometer during standardisation tests.

The intra-individual variability of the subjects undergoing Protocol 1 for both MEP and MIP was general small (range 1.1 to 3.0%), statistically non significant and comparable across occasions. In contrast, the inter-individual variability, though similar across occasions was considerably higher and statistically significant (Table I). MEP and MIP values from day to day and week to week were not significantly different from each other (Table II). During the first day of measurement the three values of MEP and MIP were similar to each other, excluding a "short term" training effect. Values for the two parameters were also similar on the three separate days of measurement, thus excluding a "long term" training effect (Table III).

TABLE I : Intra and Inter-individual variability of Maximal expiratory and inspiratory pressures on three separate occasions.

	Intra-individual variation		*Inter-individual variation*	
	MEP	*MIP*	*MEP*	*MIP*
Occasion 1	2.2%	2.5%	28.6%**	41.2%**
Occasion 2	1.1%	2.5%	27.3%**	37.3%**
Occasion 3	3.0%	1.2%	32.1%**	38.6%**

Variability calculated from the 'true variance' obtained from the ANOVA Table.
**P<0.01

Data obtained from Protocol 2 revealed that there was no diurnal variation in MEP over the 12 hours that we performed measurements (Fig. 3). In contrast, there was a significant change in MIP values (Repeated measures ANOVA, P<0.01). Inspiratory pressure values at 8 a.m were smaller than the daily mean, but achieved values around the mean two hours later, by 10 a.m.

TABLE II : Day to day and week to week variation in maximum expiratory and inspiratory pressures.

	MEP	*MIP*
Day 1	72.4 ±22.4	61.4 ± 22.2
Day 2	74.2 ±21.4	65.0 ± 21.6
Week 1	66.8 ±178.3	60.9 ± 19.6
Week 2	74.3 ±23.0	64.8 ± 23.1

Mean ± SD.
There were no significant differences in MEP and MIP from day to day or week to week.

TABLE III : A comparison of MEP and MIP across three separate occasions (i.e. Day 1, 2, 9 or Day 1, 8, 9).

	Occasion 1	*Occasion 2*	*Occasion 3*
MEP	64.9 ±19.4	73.2 ± 23.1	73.6 ± 23.1
MIP	57.2 ±22.7	62.6 ± 22.5	62.6 ± 22.5

Mean ± SD.
Repeated measures ANOVA did not reveal any significant differences.

47 subjects (22 male, 25 female) between the ages of 18 and 28 years underwent Protocol 3. These subjects had a large range of BMI (16.0 to 32.8 kg/m^2), MEP (36 to 192 mm Hg) and MIP (–22 to –97 mm Hg). There was a significant positive correlation between MEP and MIP (r=0.68, P<0.01). For the entire group, the mean MIP was ~ 84% of the mean MEP; this was statistically significant (MIP, 65.5 ± 21.2 vs. MEP, 77.7 ± 32.7 mm Hg, P<0.01). There were clear gender differences in the respiratory pressures recorded with males having significantly higher maximal inspiratory (79.9 ± 19.1 vs. 53.6 ± 15.0) and expiratory

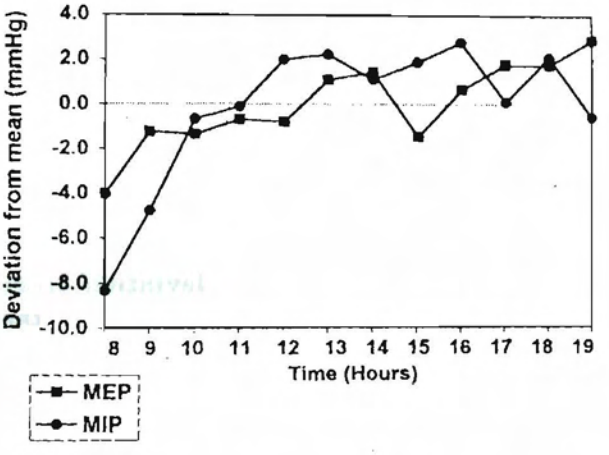

Fig. 3 : Diurnal variation in Maximal Expiratory Pressure and Maximal Inspiratory Pressure.

pressures (97.9 ± 35.8 vs. 60.5 ± 17.7 mm Hg) than females.

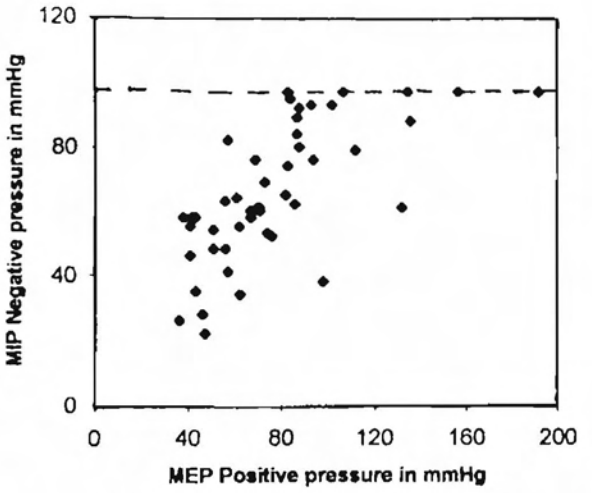

Fig. 4 : The relationship between maximal expiratory and inspiratory pressures in a heterogenous group of healthy adults. The dashed line indicates the limit of detection for inspiratory pressures.

DISCUSSION

We have described a simple, economical and portable device that can be used to measure maximal expiratory and inspiratory pressures. The original instrument of Black and Hyatt (9) coupled the mouthpiece to two diaphragm gauges, one for the positive pressure measurement and the other for the negative pressure. While the positive pressure gauge is easily obtained using the gauge of an aneroid syphgmomanometer, currently available negative pressure gauges are relatively expensive and large, making the non-digital form of the instrument more cumbersome to use.

The instrument that we devised cost a total of approximately Rs. 3,500. There are, however, possibilities of enhancing the scope of the instrument, albeit at added cost. Additional features or extension of existing features that could be incorporated into the instrument include:

1. Extending the range of negative pressures. In this instrument the range for negative pressures of the instrument was–96 mm Hg. This limit was achieved by 5 male subjects undergoing protocol 3. While the limit of detection in the present instrument is well above the requirement for clinical use in determining weaning from ventilation (4) and probably for the investigation of neuromuscular disorders (3, 7), an extended range may be of use while studying respiratory strength in healthy volunteers.

2. The current instrument runs on a 9V DC adaptor connected to 230 V AC 50 Hz. It would be possible to incorporate a chargeable battery unit within the instrument so that it could be even more portable.

3. At present the determination of peak pressure is done by picking out the maximal pressure recorded on the display unit. A "peak holding" facility could be incorporated into the circuitry.

4. It is possible to also extend the use of the instrument so that it can store serial data and recall this data in sequence.

The present study also outlines some of the characteristics of the measurement of maximal respiratory pressures in human subjects. The data demonstrates that the intra-individual variability is small and

comparable across different days of measurement. The data of variability in these parameters, is important in the estimation of sample size in future studies. The data also showed that there was no evidence of any training effect in the measurement of maximal expiratory and inspiratory pressures either in the short or long term. This is important because it suggests that the first measurement made on a patient or subject is likely to be the true value. There was no diurnal variation in maximal expiratory pressure. In contrast, maximal inspiratory pressures were smallest early during the day, then increased to higher values by about 10 am, and were then maintained at this level for the rest of the day. This would suggest that respiratory muscle function testing using maximal pressures is best avoided early in the morning.

There was a positive correlation between maximal expiratory and inspiratory pressures. The strength of the correlation was similar to that reported in earlier studies (9). In this data set, maximal inspiratory pressure was 84% of MEP. The gender differences that we demonstrated are similar to the findings in other ethnic groups (9,10). The concordance of our data with those earlier reported, particularly in uncovering inter-group differences, highlights the discriminatory power of the instrument.

In conclusion, we have described the construction and validation of a digital peak, respiratory pressure monitor. The characteristics of these measurements in relation to variability, diurnal variation and gender differences have also been described.

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